To: Dockets Management Branch (HFA-305)
5630 Fishers Lane
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Subject: Docket No. 99N-1737

1. There is a public health need for inclusion of device investigations within the scope of the data bank under 402(j) of the PHS Act.

According to FDA's classification of devices, Class III devices include ligament replacements and bone substitute. Class III includes those devices for which general regulatory controls are not sufficient to assure safety and effectiveness and there is not sufficient information to establish a performance standard. Class III devices are generally considered investigational and have generally not been cleared for marketing for a particular purpose by the FDA. Class III devices also include all devices introduced after the enactment of the 1976 Amendments that are not substantially equivalent to a device marketed prior to enactment.

Class III devices may present a substantial risk to the public.

Upon a manufacturer's petition to FDA, a medical device may be reclassified from Class III to Class II or I.

It is legally permissible for a physician to use a commercially available and marketed medical device according to the physician's best medical knowledge and judgment, even if the medical device has not been cleared for that particular use by the FDA.

The decision rendered by U. S. District Court Judge Louis C. Bechtle and Judge Sandra Mazer Moss of the Court of Common Pleas of Philadelphia County mandates that in the litigation and for all further pedicle screw cases presented in Philadelphia, the law of informed consent does not require a physician to disclose to a patient whether or not a device has been given a regulatory or administrative label by the FDA. "A physician is free to use a medical device for an off-label purpose if, in the physician's best medical judgment, he or she believes that the use of the device will benefit the patient," the judges wrote in the decision. "Because the off-label use of a medical device is a matter of medical judgment, a physician may be subject to medical malpractice liability for the exercise of that judgment. That physician cannot, however, be held liable under the doctrine of informed consent for failing to advice a patient that a particular device has been given an administrative or regulatory label by the FDA."

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The ruling essentially nullifies the physician's duty to tell a patient that a particular medical device has been labeled by the FDA as a "Class III" device, an "investigational device" or a "significant risk" device. The ruling has significant implications for other states.

In 1995 Medicare extended its coverage to pay for new generations of medical devices while they are still being studied for marketing approval. This policy means that Medicare will pay for most medical devices prior to marketing approval, when they are used as a part of an approved clinical trial. Medicare rates are the same for comparable approved devices. Medicare coverage for devices in clinical trials accelerated the use of these devices for older persons. The continued growth of the older adult population means that the use of medical devices will increase dramatically as older adults search for ways to deal with arthritis and osteoporosis.

Hip and knee replacement arthroplasty are by far the most commonly performed replacements. Shoulder, elbow, finger, and toe joint replacements are showing steady increases.

The success rate of ligament replacement operations is difficult if not impossible to access. However, faulty replacements are occurring. The literature consistently ties success rates to the experience of the physician. Personally, I know of one 51 year old Oklahoma woman who has had three hip replacement operations within the last 10 years.

The ethics of reuse of single-use devices of medical devices, which appears to be a legitimate question, is being debated at medical conferences. These discussions have centered around informed patient consent, cost versus benefits of reuse, and the need for further scientific studies and patient tracking. For patients covered by Diagnosis Related Groups, billing is not affected by the lower cost of a reprocessed single-use device.

Throughout its history, FDA has been overly cautious about the intersection of its legal authority to protect the public health and ability of physicians to practice medicine and surgery as they believe is most appropriate and in the best interest of their patients. This hesitation has resulted in increased patient risks and abuse, as well as increased costs and fraud.

2. Because a public health need does exist, categories I, II, and III, as well as all seven categories which relate to the 1976 amendment, medical device trials should be make publicly available and communicated in a consumer-oriented manner. Data banks for IDEs should not be restricted and data bank must be inclusive of all studies.

Public disclosure of this information is vital to patient decision-making. Fully informing patients of the risks and benefits of treatment options tends to improve patient outcomes and reduce costs, as well as fraud. The Foundation for Informed Medical Decision-Making, along with other consumer groups, supports the shared decision-making theory.

To transform this theory into shared decision-making practices, consumers must be empowered to make the types of decisions that makes it possible for a physician and a patient to make a treatment selection that reflects, not only important clinical considerations, but also the values and preferences of the patient.

Many consumers agree with the bodies that several major trends in health care today create the need for a more informed and empowered medical consumer. Primarily,

1) The need to reduce medical care costs. Thus far most efforts have focused on managed care efforts to reduce supplier demands, with little concern for services that appear to be neither needed nor consistent with patients' preferences.

2) Public dissatisfaction with the health care system is growing. This dissatisfaction can be traced to patients' frustration with the paternalistic system of both fee-for-service and managed care.

3) Consumers want more information and want to be involved in managing their health and health care. More and more consumers are turning to the media for answers about their health care needs, and this has resulted in increased media coverage and publications related to health care. Too often much of the information they receive may not be evidence-based and thusly inadequate for medical decision making.

4) The Internet is providing unparalleled information access. According to Cyber Dialog, an Internet research firm, more than 17 million U. S. adults searched 20,000 web sites for health and medical information in 1998. Increased access to information shows that medical opinion and treatment practices vary from physician to physician and region to region. As a result, there is an increased demand for unbiased evidence-based material.

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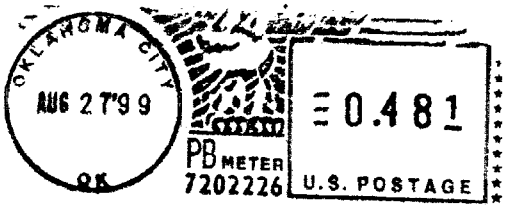

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